



1.0 Goals

The goal of this REMS is to effectively communicate the potential risk of rhabdomyolysis when Trilipix and statins are co-administered, by providing a Medication Guide with Trilipix delayed release capsules.

2.0 REMS Elements

2.1 Medication Guide

In compliance with 21 CFR Part 208, Abbott has created a Medication Guide for Trilipix, based on the information provided in the Full Prescribing Information (FPI) for Trilipix. The proposed Medication Guide appears in Section 17.2 of the FPI. The Medication Guide has been written in a manner intended to be easily understood by a patient. It describes the risks of the co-administration of Trilipix and statins in such a way as to provide the patient with the necessary information, so that they, along with their doctor, can decide if Trilipix co-administered with statins is the right treatment for their mixed dyslipidemia.

In accordance with 21 CFR 208.24(b), Abbott will ensure that the Medication Guide is available for distribution to patients by providing Medication Guide in sufficient numbers to distributors, packers or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a sample or a prescription of Trilipix.

Trilipix delayed release capsules are provided in unit-of-use samples in 7-count and 28-count sizes, or in commercial (pharmacy) bottles of 90 capsules. One copy of the approved FPI, including the Medication Guide, will be provided with each unit-of-use sample. One copy of the approved FPI, with three copies of the Medication Guide, will be provided with each commercial bottle of 90 capsules. In addition, Abbott will provide tear-pads of Medication Guide to authorized dispensers, as an additional method of providing the Medication Guide information to patients at the point of dispensing.



Additionally, the FPI, including the Medication Guide, will also be available on the Internet at www.trilipix.com.

In accordance with 21 CFR 208.24(d), Abbott has also included a statement on the Trilipix container labels to alert pharmacists to dispense the Medication Guide with the product.

2.2 Communication Plan

This REMS for Trilipix can be approved without a Communication Plan.

2.3 Elements to Assure Safe Use

This REMS for Trilipix can be approved without any elements to assure safe use.

2.4 Implementation System

Because this REMS for Trilipix can be approved without any elements to assure safe use, an implementation system is not required.

2.5 Timetable for Assessments

- 1st FDAAA assessment: To cover the interval from the date of approval to May 31, 2010 (18 months from approval). The assessment will be submitted no later than July 30, 2010.
- 2nd FDAAA assessment: To cover the interval from June 1, 2010 to November 30, 2011 (3 years from approval). The assessment will be submitted no later than January 31, 2012.
- 3rd FDAAA assessment: To cover the interval from December 1, 2011 to November 30, 2015 (7 years from approval). The assessment will be submitted no later than January 31, 2016.